

## § 524.1880

adult animal. Lesser amounts will permit runoff for younger animals.

(iii) *Pour-on method.* Dilute the drug with water according to table by slowly adding water to the product while stirring. Apply 1 ounce of the diluted mixture per 100 pounds of body weight (to a maximum of 8 ounces per head) down the center line of the back.

(2) *Timing of applications for cattle grub control.* For optimum cattle grub control, it is important to treat as soon as possible after the heel fly season, before the grub larvae reach the gullet or spinal canal, as the rapid kill of large numbers of larvae in these tissues may cause toxic side effects, such as bloat, salivation, staggering, and paralysis.

(3) *Treatment regimens.* (i) Control of scabies mites requires two treatments, 10 to 14 days apart.

(ii) Control of Lone Star Ticks and hornflies requires two treatments, 7 days apart.

(4) *Warnings.* The drug is a cholinesterase inhibitor. Do not use this drug on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not apply within 21 days of slaughter. For use on beef cattle only. Do not treat sick, convalescent, or stressed cattle, or calves less than 3 months old except in Federal or State eradication programs where immediate treatment of all animals in an infested herd is mandatory. Be sure free access to drinking water is available to cattle prior to dipping. Do not dip excessively thirsty animals. Do not dip animals when overheated. Repeat treatment as necessary but not more often than every 7 to 10 days. Treatment for lice, ticks, hornflies, and scabies mites may be made any time of the year except when cattle grub larvae are in the gullet or spinal canal. Treatment for lice, ticks, and scabies mites may be made any time 7 to 10 days following treatment for grubs. Do not treat grubs when the grub larvae are in the gullet or spinal canal. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wear rubber gloves, goggles, and protective clothing. In case of skin contact, wash immediately with soap and water; for eyes, flush with

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water. Wash all contaminated clothing with soap and hot water before re-use.

(d) *Related tolerances.* See 40 CFR 180.261.

[40 FR 13873, Mar. 27, 1975, as amended at 46 FR 27914, May 22, 1981; 48 FR 39607, Sept. 1, 1983; 54 FR 51021, Dec. 12, 1989; 61 FR 8873, Mar. 6, 1996; 62 FR 61626, Nov. 19, 1997; 63 FR 5255, Feb. 2, 1998]

### § 524.1880 Prednisolone-neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Prednisolone-neomycin sulfate ophthalmic ointment contains 2 milligrams prednisolone and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants. A small quantity of the ointment should be expressed into the conjunctival sac four times a day for 7 days. After 7 days, if clinical improvement is not noted, re-evaluation of the diagnosis should be considered. All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway. For use only by or on the order of a licensed veterinarian.

### § 524.1881 Prednisolone acetate ophthalmic and topical dosage forms.

#### § 524.1881a [Reserved]

#### § 524.1881b Prednisolone acetate-neomycin sulfate sterile suspension.

(a) *Specifications.* Prednisolone acetate-neomycin sulfate sterile suspension contains 2.5 milligrams of prednisolone acetate and 5 milligrams of neomycin sulfate (equivalent to 3.5 milligrams of neomycin base) in each milliliter of sterile suspension.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for treating infectious, allergic and traumatic keratitis and conjunctivitis, acute otitis externa, and chronic otitis externa in dogs and cats.

(2) For beginning treatment of acute ocular inflammations 1 or 2 drops may be placed in the conjunctival sac 3 to 6 times during a 24 hour period. When improvement occurs, the dosage may be reduced to 1 drop 2 to 4 times daily. In otitis externa, 2 to 6 drops may be placed in the external ear canal 2 or 3 times daily.

(3) All topical ophthalmic preparations containing corticosteroids with or without an anti-microbial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**§ 524.1883 Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment.**

(a) *Specifications.* Prednisolone sodium phosphate-neomycin sulfate ophthalmic ointment contains prednisolone sodium phosphate equivalent to 2.5 milligrams prednisolone 21-phosphate and 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base) in each gram of ointment.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended for use in superficial ocular inflammations or infections limited to the conjunctiva or the anterior segment of the eye of cats and dogs, such as those associated with allergic reactions or gross irritants.<sup>1</sup>

(2) A small quantity of the ointment should be expressed into the conjunctival sac 4 times a day (at intervals of 1 to 8 hours) for a few days until there is a favorable response, then the frequency of application may be reduced to twice daily as long as the condition

remains under control. Treatment may require from a few days to several weeks.<sup>1</sup>

(3) All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well underway.<sup>1</sup>

(4) For use only by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

**§ 524.1982 Proparacaine hydrochloride ophthalmic solution.**

(a) *Specifications.* The drug is an aqueous solution containing 0.5 percent proparacaine hydrochloride, 2.45 percent glycerin as a stabilizer, and 0.2 percent chlorobutanol (choral derivative) and 1:10,000 benzalkonium chloride as preservatives.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Special considerations.* The longterm toxicity of proparacaine is unknown. Prolonged use may possibly delay wound healing.

(d) *Conditions of use.* (1) The drug is indicated for use as a topical ophthalmic anesthetic in animals. It is used as an anesthetic in cauterization of corneal ulcers, removal of foreign bodies and sutures from the cornea, and measurement of intraocular pressure (tonometry) when glaucoma is suspected. Local applications may also be used as an aid in the removal of foreign bodies from the nose and ear canal, as an accessory in the examination and treatment of painful otitis, in minor surgery, and prior to catheterization.

(2) It is administered as follows:

(i) For removal of sutures: Instill one to two drops 2 or 3 minutes before removal of stitches.

(ii) For removal of foreign bodies from eye, ear, and nose: For ophthalmic use, instill three to five drops in the eye prior to examination; for otic use, instill five to 10 drops in the ear; for nasal use, instill five to 10 drops in each nostril every 3 minutes for three doses.

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.